Attorney Docket mber: GIN-6006B4

## What is claimed:

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- 1. A method for identifying a compound capable of treating or preventing preeclampsia comprising:
  - a) contacting a cell with a test compound;
- b) determining whether expression or activity of syncytin in the cell is modulated in the presence of the compound; and
- c) identifying the compound as being capable of treating or preventing preeclampsia based on the ability of the compound to modulate expression or activity of syncytin.
- 2. The method of claim 1, wherein the ability of the test compound to modulate syncytin activity in the cell is determined by detecting the ability of the test compound to modulate the cellular localization of syncytin in the cell.
- 3. The method of claim 1, wherein the ability of the test compound to modulate syncytin activity in the cell is determined by detecting the ability of the test compound to modulate fusion between the cell and a second cell.
- 4. The method of claim 1, wherein the ability of the compound to modulate syncytin expression is determined by detecting syncytin expression and comparing said expression to a suitable control.
- 5. The method of claim 1, wherein the cell is selected from the group consisting of a placental cell, a cytotrophoblast, a syncytiotrophoblast, a cell comprising or transfected with a nucleic acid molecule encoding a syncytin polypeptide, and a cell comprising or transfected with a nucleic acid molecule comprising at least one syncytin regulatory element operatively linked to a reporter gene.
  - 6. The method of claim 1, wherein the expression or activity of syncytin is increased.

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- 7. A compound identified according to the method of claim 1.
- 8. A prognostic method for determining whether a subject is at risk for developing preeclampsia comprising detecting the presence or level of syncytin mRNA or polypeptide in a biological sample obtained from said subject, or isolate of said sample, thereby determining that the subject is at risk for developing preeclampsia based on the presence or level of syncytin detected.
- 9. A diagnostic method for determining whether a subject has

  preeclampsia comprising detecting the presence or level of syncytin mRNA or
  polypeptide in a biological sample obtained from said subject, or isolate of said
  sample, thereby determining that the subject has preeclampsia.
- 10. The method of claim 9, further comprising comparing the level of
  syncytin mRNA or polypeptide in the biological sample obtained from said subject, or
  isolate of said sample, to the level of syncytin of mRNA or polypeptide in an
  appropriate control.
- 11. The method of claim 9, wherein the biological sample is selected from the group consisting of a tissue sample, a tumor sample, an endothelial cell sample, a plasma sample, and a blood sample.
  - 12. The method of claim 9, wherein the biological sample is a serum sample.
  - 13. The method of claim 9, wherein the biological sample is selected from the group consisting of an amniotic fluid sample, a chorionic villus sample, and a placental sample.
- 30 14. The method of claim 9, further comprising detecting the presence or level of at least one additional factor in said biological sample.

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- 15. The method of claim 14, wherein said additional factor is selected from the group consisting of TNF $\alpha$  mRNA, TNF $\alpha$  polypeptide, M-CSF mRNA, and M-CSF polypeptide.
- 5 16. The method of claim 14, further comprising comparing the level of said additional factor to a suitable control.
  - 17. The method of claim 9, wherein the level of syncytin is determined during the first trimester of pregnancy.
  - 18. The methods of claim 9, wherein the level of syncytin is determined at approximately 14 to 16 weeks of gestation.
- 19. A method for treating a subject having or at increased risk for preeclampsia comprising administering a therapeutically effective amount of a syncytin modulator, such that said preeclampsia is treated or prevented.
- 20. The method of claim 19, wherein said therapeutically effective amount of a syncytin modulator comprises an amount sufficient to bring serum syncytin levels to normal serum syncytin levels.
  - 21. The method of claim 19, further comprising administering a therapeutically effective amount of M-CSF.
- 25 22. The method of claim 19, further comprising administering a therapeutically effective amount of a TNFα inhibitor.
- The method of claim 19, further comprising administering a therapeutically effective amount of M-CSF and a therapeutically effective amount of
   a TNFα inhibitor.
  - 24. The method of 22, wherein the TNFα inhibitor is etanercept.

- 25. The method of claim 19, wherein said syncytin modulator is administered late during the first trimester or during the second trimester of pregnancy.
- The methods of claim 19, wherein said syncytin modulator is administered beginning at approximately 14 to 16 weeks gestation and ending at approximately 30 weeks gestation.
- 27. The methods of claim 19, wherein said syncytin modulator is
  administered beginning at approximately 14 to 16 weeks gestation and continuing
  until normal serum syncytin levels are achieved.
  - 28. A method for treating a subject having a gestational trophoblast disorder, said method comprising administering a therapeutically effective amount of a syncytin modulator.
    - 29. The method of claim 28, wherein said gestational trophoblast disorder is selected from the group consisting of a missed or incomplete abortion, choriocarcinoma, hydatiform mole, and placental site tumor.
    - 30. A method for treating a subject having a gestational trophoblast disorder, said method comprising administering a therapeutically effective amount of a syncytin modulator, wherein said syncytin modulator is a compound identified according to the method of claim 1.
  - 31. A kit for use in determining whether a subject has or is at risk for preeclampsia comprising a means for detecting syncytin mRNA or polypeptide in a biological sample or isolate thereof.
- 32. The kit of claim 31, wherein said means for detecting syncytin mRNA or polypeptide is a labeled or labelable agent capable of detecting syncytin mRNA or polypeptide.

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- 33. The kit of claim 32, wherein the agent is a nucleic acid probe capable of hybridizing to syncytin mRNA.
- 34. The kit of claim 32, wherein the agent is an antibody capable of specifically binding to syncytin polypeptide.
  - 35. The kit of claim 31, further comprising an appropriate control.
  - 36. The kit of claim 31, further comprising directions for use.